

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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Application of: **Roose**

Serial No.: **10/748,316**

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Group Art Unit: **3737**

Examiner: **Amanda L. Lauritzen**

For: **System And Method Of Designing And Manufacturing Customized
Instrumentation For Accurate Implantation Of Prosthesis By Utilizing
Computed Tomography Data**

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APPEAL BRIEF

Sir:

This is an appeal under 37 CFR § 41.31 to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office from the rejection of the claims 1-15 and 17-21 of the above-identified patent application. These claims were indicated as rejected in an Office Action dated December 10, 2008. The \$540.00 fee required under 37 CFR § 41.20(b) (2) has been submitted herewith. Also, please provide any extensions of time that may be necessary and charge any fees that may be due to Account No. 13-0014, but not to include any payment of issue fees.

(1) REAL PARTY IN INTEREST

DePuy Products, Inc. of Warsaw, Indiana is the assignee of this patent application, and the real party in interest.

(2) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this patent application (serial no. 10/748,316).

(3) STATUS OF CLAIMS

Claim 16 has been canceled.

Claims 1-15 and 17-21 are rejected.

Claims 1-15 and 17-21 are being appealed, and are shown in the Appendix attached to this Appeal Brief.

(4) STATUS OF AMENDMENTS

Appellants have not filed any amendment after receipt of the December 10, 2008, Office Action (the "Office Action").

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates a system and method for designing and making a surgical guide for a joint socket in which bone anatomical data regarding a patient's joint is used to design and make the surgical guide. A method for designing a surgical guide for a joint replacement prosthesis comprises generating a bone surface image from three

dimensional bone anatomical data corresponding to a patient's bone, generating a surgical guide image from the generated bone surface image and an image of a prosthetic imposed on the bone surface image, and generating control data from the surgical guide image so that the operation of a machine for fabricating a surgical guide may be controlled to produce a surgical guide that corresponds to the surgical guide image. The three dimensional bone anatomical data may be computed tomography data of a bone in which a prosthesis corresponding to the prosthetic image will be implanted. (See, e.g., Appellant's specification at page 6, lines 7-19).

The additional information required by the United States Patent Office is as follows.

Claim 1

Claim 1 is an independent claim. Claim 1 recites:

A method for designing a surgical guide for a joint replacement prosthesis comprising structure (see, e.g., Appellants' specification at Abstract):

generating a bone surface image from three dimensional bone image data of a patient's bone (see, e.g., Appellants' specification at page 12, lines 4-20 and FIGs. 1a, 1b, and 1c);

generating a surgical guide image from the bone surface image and an image of a prosthetic implant imposed on the bone surface image (see, e.g., Appellants' specification at page 13, lines 10-19 and FIGs. 3a, 3b, and 3c); and

generating control data from the generated surgical guide image, the control data being used to control operation of a machine to fabricate a surgical guide (see, e.g., Appellants' specification at page 14, lines 18-27, page 15, lines 10-16, and FIG. 5).

Claim 8

Claim 8 is an independent claim. Claim 8 recites:

A system for designing a surgical guide for a joint replacement prosthesis comprising (see, e.g., Appellants' specification at Abstract):

a bone surface image generator for forming a bone surface image from three dimensional bone anatomical data for a patient's bone (see, e.g., Appellants' specification at page 12, lines 4-20 and FIGs. 1a, 1b, and 1c);

a surgical guide image generator for generating a surgical guide image from the bone surface image and an image of a prosthesis implant imposed on the bone surface image (see, e.g., Appellants' specification at page 13, lines 10-19 and FIGs. 3a, 3b, and 3c); and

a surgical guide image converter for generating control data to control operation of a machine for fabricating a surgical guide that corresponds to the surgical guide image (see, e.g., Appellants' specification at page 14, lines 18-27, page 15, lines 10-16, and FIG. 5).

Claim 15

Claim 15 is an independent claim. Claim 15 recites:

A system for aiding a surgeon in a joint replacement operation comprising (see, e.g., Appellants' specification at Abstract):

a patient bone data repository for storing three dimensional data of a patient's bone (see, e.g., Appellants' specification at page 12, lines 4-20, page 17, lines 23-28, FIGs. 1a, 1b, and 1c, and FIG. 8);

a reference pointer for providing positional data of a surgical site (see, e.g., Appellants' specification at page 17, lines 23-27, page 18, lines 10-20, and FIG. 8);

a registration module (see, e.g., Appellants' specification at page 17, lines 23-27, and FIG. 8) for (i) receiving the positional data (see, e.g., Appellants' specification at page 18, lines 21-30, and FIG. 8), (ii) correlating the positional data for the surgical site obtained from the reference pointer to the three dimensional data for the bone stored in the patient bone repository (see, e.g., Appellants' specification at page 18, lines 21-30, and FIG. 8), and (iii) determining changes in the surface of the bone using the received positional data (see, e.g., Appellants' specification at page 19, lines 11-16, and FIG. 8); and

an image generator for generating an image of the patient's bone with an image of a prosthetic implant imposed on the image of the patient's bone (see, e.g., Appellants' specification at page 13, lines 10-19 and FIGs. 3a, 3b, and 3c).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claim 18 and the drawings are objected to under 37 CFR 1.83(a) as reciting structure not depicted in the drawings.

Claims 15 and 17-21 stand rejected under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement.

Claims 1-15 and 17-21 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 1-7 and 8-14 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Publication No. 2003/0216669 to Lang et al. (hereinafter “Lang”) in view of U.S. Patent Publication No. 2003/0236473 to Dore et al. (hereinafter “Dore”).

Claims 15 and 17-21 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Publication No. 2002/0147455, now U.S. Patent No. 6,923,817 to Carson et al. (hereinafter “Carson”).

(7) ARGUMENT

Claim 18 Structure is Sufficiently Shown

Claim 18 and the drawings are objected to under 37 CFR 1.83(a) as reciting structure not depicted in the drawings. (Office Action at page 3). The “objection” to claim 18 and the drawings and the rejection of claim 18 under the first paragraph of 35 U.S.C. § 112 raise, however, a single issue. Namely, whether or not one of ordinary skill in the art, given the Appellant’s disclosure, would be enabled to make and/or use the invention of claim 18. Since one of ordinary skill in the art, given the Appellant’s disclosure, would be enabled to make and/or use the invention of claim 18, the objection to claim 18 and the drawings should be reversed.

1. The Objection to Claim 18 is Resolved by 112 Analysis

The Examiner objected to claim 18 contending that an “articulating arm with positional gyros mounted at pivotal joints of the articulating arm” was not shown in the drawings, and that 37 CFR 1.83(a) includes a requirement that a “drawing in a nonprovisional application must show every feature of the invention specified in the claims.” (Office Action at page 3).

In responding to the same rejection in an earlier office action, the Appellant noted that 37 CFR 1.83(a) further states:

[C]onventional features disclosed in the description and claims, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation (e.g., a labeled rectangular box).

FIG. 8 of the Appellant’s specification depicts a “reference pointer” 208 as a rectangular box. The reference pointer 208, in one embodiment, is described as “implemented with an articulating arm having positional gyros at each arm joint to provide positional data regarding movement of an articulating arm joint.” (Appellant’s specification at page 18, lines 11-14). Therefore, if an articulating arm having positional gyros at each arm joint is a conventional feature, then the objection to claim 18 and the drawings is improper.

In response to the Appellant’s earlier argument, the Examiner stated that “the phraseology is not conventional within the art and it is not clear what the applicant intends to embody in the invention.” (Office Action at page 2). In rejecting claim 18 under the first paragraph of 35 U.S.C. § 112, the Examiner similarly contended that because “an articulating arm with positional gyros mounted at pivotal joints of the

articulating arm” is not depicted in the drawings, “[i]t is not clear how one would make or use the invention.”

Accordingly, if the limitation of “an articulating arm with positional gyros mounted at pivotal joints of the articulating arm” would be understood by one of ordinary skill in the art in view of the Appellant’s specification, then claim 18 is enabled, and the depiction of an articulating arm with positional gyros mounted at pivotal joints of the articulating arm as a rectangular box in the Appellant’s figures satisfies 37 CFR 1.83(a).

2. Articulating Arms Are Known

The Appellants previously identified a patent to the Examiner as evidence that articulating arms such as the arm recited in claim 18 and disclosed in the specification were known. In an Amendment dated July 29, 2008, the Appellant stated that “U.S. Patent No. 4,942,598 to Yuan et al. (hereinafter “Yuan”) describes a robotic arm that includes sensors to characterize the movement of the arm. (See, e.g., Yuan at Abstract).” As noted by the Examiner, the identified patent number included a typographical error. Rather than the number submitted, the patent number should have read “4,942,538.” Notwithstanding the typographical error, the Yuan patent is easily discovered by a search of the USPTO database for the terms “Yuan” and “robotic” (one of 38 references).

More significantly, however, is the fact that a search for “articulating arm” reveals a number of patents, all of which the Board may take Official Notice of. By way of example, U.S. Patent No. 6,085,749, entitled “Endoscopic robotic surgical tools and methods” discloses “articulating arms 15, 215.” (See also U.S. Patent No. 7,055,789, entitled “Articulating Tool Arm with Positional Feedback”). Thus, the term “articulating

arm” is a commonly used term and readily understood by those of ordinary skill in the relevant art.

3. Position Feedback Was Known

As evidenced by the foregoing patents, systems for providing positional feedback were also known. Claim 18, of course, identifies a specific type of feedback device, namely, “positional gyros.” “Positional gyros” were known for many years preceding the filing of the Appellant’s application. (See, e.g., U.S. Patent No. 4, 080,655, which issued on March 21, 1978).

4. Conclusion

Therefore, because all of the terms used in claim 18 are readily understood by one of ordinary skill in the art, even without reference to the Appellant’s application, one of ordinary skill in the art, given the Appellant’s disclosure, would be enabled to make and/or use the invention of claim 18. Therefore, claim 18 is enabled, and the representation of a reference pointer, which in one embodiment is an articulating arm with positional gyros, as a rectangular box satisfies the requirements of 37 CFR 1.83(a). Accordingly, the Board of Appeals is respectfully requested to reverse the objection to claim 18 and the objection to the drawings.

Claims 15 and 17-21 are Supported by the Specification

Claims 15 and 17-21 stand rejected under 35 U.S.C. § 112 first paragraph as failing to comply with the written description requirement. The subject matter of claims

15 and 17-21 is described in the specification in sufficient detail that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention. Therefore, the rejection of claims 15 and 17-21 should be reversed.

Discussion re: Claim 15

The Examiner has opined that the limitation in claim 15 of “determining changes in the surface of the bone using the received positional data” “cannot be corresponded to applicant’s disclosure.” (Office Action at page 4). The limitation identified by the Examiner is disclosed in the specification.

In support of her position, the Examiner cites to paragraph 49 as proof that the foregoing limitation was not disclosed in the application. (Office Action at page 4). Paragraph 49, which the Appellant believes to refer to the published version of the Appellant’s specification, corresponds to an overview of the system of FIG. 8 at page 17, line 23 through page 18, line 20. The overview of the system identified by the Examiner discussed the capabilities of the system to include correlation of a pointer position to stored image data. (Appellant’s specification at page 18, lines 17-20). This action would occur prior to performance of the limitation of claim 15. Thus, while the Examiner correctly notes that the limitation of claim 15 is not found in this particular passage, one would not reasonably expect the limitation of claim 15 to be in the passage.

Moreover, absence of a particular limitation in a passage apparently selected by random is not determinative of whether or not a limitation is disclosed. The issue is more appropriately cast as whether or not the limitation is disclosed in the Appellant’s

specification as a whole. At page 18, line 21 through page 19, line 3, the Appellant's specification states:

The registration module 214 receives positional data from the reference pointer 208 and correlates a position corresponding to the positional data to a point on the surface of the volumetric image stored in the repository 204. At least three surface points are required for the registration module 214 to establish a correlation between the volumetric image stored in the repository 204 and the surgical site. The registration module 204 performs this function by receiving positional data from the reference pointer 208 and correlating the positional data to the image data stored in the repository 204 so the three dimensional patient bone data may be oriented to the patient's body position on the surgical table. Once registration is achieved, an image may be generated from any perspective. The perspective may be defined by an angular orientation of the reference pointer 208 or it may be specified by the surgeon.

The "volumetric image" refers to data described at page 17, line 27 through page 18, line 1 which is three dimensional data derived from, e.g., "CT data of a patient's joint."

Thereafter, page 19, lines 11-16 states:

As bone is removed, the registration module 214 determines that the surface points of the volumetric data are changing. Consequently, the image presented by the image generator 218 changes to show the surgeon the changes to the implant site and what remains to be removed before the site is ready to receive the implant.

Thus, the Appellant's specification specifically discloses the limitation in claim 15 of "determining changes in the surface of the bone using the received positional data". Accordingly, because the subject matter of claim 15 is described in the specification in sufficient detail that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention, the Board of Appeals is respectfully requested to reverse the rejection of claim 15.

Discussion re: Claim 17

While claim 17 was identified by the Examiner as rejected under 35 U.S.C. § 112 first paragraph (Office Action at page 4), the Examiner does not identify any reason for the rejection. Since claim 17 depends from claim 15, the Appellants believe the rejection is based solely upon the dependency of claim 17 on claim 15. Accordingly, because the rejection of claim 15 should be reversed for the reasons set forth above, the rejection of claim 17 should also be reversed for the reasons set forth above.

Discussion re: Claim 18

Claim 18 was rejected for not enabling “an articulating arm with positional gyros mounted at pivotal joints of the articulating arm.” (Office Action at page 5). As discussed above with respect to the objection to claim 18 and the drawings, one of ordinary skill in the art, given the Appellant’s disclosure, would be enabled to make and/or use the invention of claim 18. Accordingly, the rejection of claim 18 should be reversed.

Discussion re: Claim 21

The Examiner has opined that the limitation in claim 21 of identifying “the portion of a bone remaining to be excised based upon the received positional data” “is not supported by the specification. (Office Action at page 5). The limitation identified by the Examiner is disclosed in the specification.

Specifically, the Examiner cites to “paragraph [0038]” for the proposition that “removal of ‘portions of flanges’ is specified but these understood (sic) as part of the

implant and not part of the bone.” (Office Action at page 5). Paragraph “38”, which the Appellant believes to be a reference to the Appellant’s specification as published, corresponds to page 13, lines 1-19, discloses a description of removing portions of a virtual image of an acetabular cup. Thus, the passage identified by the Examiner does not appear to support the limitation of claim 21.

As discussed above, the absence of a particular limitation in a passage apparently selected by random is not determinative of whether or not a limitation is disclosed. Rather, the entire specification must be reviewed. A review of the Appellant’s specification shows that the limitation of claim 21 is clearly disclosed in the passage identified by the Appellant as disclosing the limitation. Specifically, in an Amendment dated July 29, 2008, the Appellant stated that “[s]upport for claim 21 may be found at page 19, lines 11-16 of the Applicant’s specification.” That passage, also set forth above, states:

As bone is removed, the registration module 214 determines that the surface points of the volumetric data are changing. Consequently, the image presented by the image generator 218 changes to show the surgeon the changes to the implant site and what remains to be removed before the site is ready to receive the implant.

As further noted above, at page 18, line 21 et seq., the Appellant’s specification states:

The registration module 214 receives positional data from the reference pointer 208 and correlates a position corresponding to the positional data to a point on the surface of the volumetric image stored in the repository 204.

Therefore, identifying “the portion of a bone remaining to be excised based upon the received positional data” is explicitly disclosed by the Appellant’s specification.

Accordingly, because subject matter of claim 21 is described in the specification in sufficient detail that one skilled in the art could reasonably conclude that the inventor

had possession of the claimed invention, the Board of Appeals is respectfully requested to reverse the rejection of claim 21.

Claims 1-15 and 17-21 are Statutory Subject Matter

Claims 1-15 and 17-21 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Because claims 1-15 and 17-21 are statutory subject matter, the Board of Appeals is respectfully requested to reverse the rejection of claims 1-15 and 17-21.

Discussion re: Claim 1

The Examiner has alleged that “the method steps presented” “do not positively recite any subject matter or material that is being transformed to a different state or thing.” The Examiner has failed to properly construe the claims.

Specifically, claim 1 recites “generating a bone surface image from three dimensional bone image data of a patient’s bone.” Accordingly, bone image data is converted to a bone surface image. Claim 1 further recites “generating a surgical guide image from the bone surface image and an image of a prosthetic implant imposed on the bone surface image. Based upon the generated surgical guide image, control data is generated, and the control data is *“being used to control operation of a machine to fabricate a surgical guide.”* Therefore, the claims are tied to a specific machine, to wit, a surgical guide fabricating machine.

The Federal Circuit has stated that “an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by

showing that his claim transforms an article.” *In re Bilski*, citing *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). Claim 1 recites limitations which result in the generation of control signals which are then “used to control operation of a machine to fabricate a surgical guide.” Accordingly, the claim is tied to a specific machine. Therefore, claim 1 is statutory matter.

Moreover, the claim requires “operation of a machine to fabricate a surgical guide.” Thus, a product is produced by the claimed method. Thus, practicing claim 1 “transforms an article.”

Therefore, because claim 1 is statutory matter, the Board is respectfully requested to reverse the rejection of claim 1 under 35 U.S.C. § 101.

Discussion re: Claims 2-7

Each of claims 2-7 depend from claim 1 and recite additional limitations. Accordingly, for at least the same reasons set forth above, claims 2-7 recite limitations that are limited to a specific machine.

Moreover, claims 2-7 recite additional limitations as to the type of machine (see, e.g., a “laser” in claim 4) and/or transformation of an article (see, e.g., crystallization of resin in claim 3, and selectively cutting a solid material to form a surgical guide in claim 5).

Therefore, for any or all of the foregoing reasons, each of claims 2-7 are directed to patentable subject matter the Board is respectfully requested to reverse the rejection of claims 2-7 under 35 U.S.C. § 101.

Discussion re: Claim 8

The Examiner has alleged that system recited in claim 8 is “generally directed to a process that is absent of specific apparatus and/or tangible subject matter.” (Office Action at page 6). The Examiner’s statement is apparently an attempt to legitimize the rejection of claim 8, a system claim, based upon *Bilski*. The examiner has failed, however, to provide any explanation, logic, or legal precedent in support of broadening *Bilski* to read upon a system claim.

Therefore, because claim 8 is explicitly directed to a *system*, and because the Examiner has failed to provide any rational basis for applying the rule of *Bilski* to a system claim, the Board is respectfully requested to reverse the rejection of claim 8 under 35 U.S.C. § 101.

Even if *Bilski* is applied to claim 8, however, claim 8 is tied to a specific machine and is thus statutory subject matter under the “process” analysis of 35 U.S.C. § 101. Specifically, the system of claim 8 includes an image generator (a specific machine, one embodiment of which is disclosed at Appellant’s page 12, lines 11-15 and page 16, lines 1-3), a surgical guide image generator (a specific machine, one embodiment of which is disclosed at Appellant’s page 12, lines 15-20 and page 16, lines 3-5), and a surgical guide image converter (a specific machine, one embodiment of which is disclosed at Appellant’s page 12, lines 15-20 and page 16, lines 3-5). Therefore, claim 8 is limited to a system of specific machines.

Therefore, for any or all of the foregoing reasons, claim 8 is directed to statutory matter and the Board is respectfully requested to reverse the rejection of claim 8 under 35 U.S.C. § 101.

Discussion re: Claims 9-14

Each of claims 9-14 depend from claim 8 and recite additional limitations. Accordingly, for at least the same reasons set forth above with respect to claim 8, claims 9-14 are directed to statutory subject matter.

Discussion re: Claim 15

The Examiner has alleged that system recited in claim 15 is “generally directed to a process that is absent of specific apparatus and/or tangible subject matter.” (Office Action at page 6). Like claim 8, claim 15 is explicitly directed to a *system*, and because the Examiner has failed to provide any rational basis for applying the rule of *Bilski* to a system claim, the Board is respectfully requested to reverse the rejection of claim 15 under 35 U.S.C. § 101.

Even if *Bilski* is applied to claim 15, however, claim 15 is tied to a system of specific machines and is thus statutory subject matter under the “process” analysis of 35 U.S.C. § 101. Specifically, the system of claim 15 includes a memory, a reference pointer (a specific machine, one embodiment of which is disclosed at Appellant’s page 18, lines 10-20), a registration module (a specific machine, one embodiment of which is disclosed at Appellant’s page 18, lines 10-20), and an image generator (a specific machine, one embodiment of which is disclosed at Appellant’s page 12, lines 11-15 and page 16, lines 1-3). Therefore, claim 15 is limited to a system of specific machines.

Therefore, for any or all of the foregoing reasons, claim 15 is directed to statutory matter and the Board is respectfully requested to reverse the rejection of claim 15 under 35 U.S.C. § 101.

Discussion re: Claims 17-21

Each of claims 17-21 depend from claim 15 and recite additional limitations. Accordingly, for at least the same reasons set forth above, claims 17-21 recite limitations that are limited to a specific machine. Moreover, claims 17-21 recite additional structure (see, e.g., an “articulating arm with positional gyros” in claim 18, and wireless communication in claim 19). Therefore, for any or all of the foregoing reasons, each of claims 17-21 are directed to patentable subject matter the Board is respectfully requested to reverse the rejection of claims 17-21 under 35 U.S.C. § 101.

Claims 1-7 and 8-14 are Not Obvious

Claims 1-7 and 8-14 stand rejected under 35 U.S.C. § 103(a) as being obvious over Lang in view of Dore. The Examiner has failed to establish a *prima facie* obviousness. Therefore, the Board is respectfully requested to reverse the rejection of claims 1-7 and 8-14.

Discussion Regarding Patentability of Claim 1

1. Claim 1

Claim 1 recites:

A method for designing a surgical guide for a joint replacement prosthesis comprising:

generating a bone surface image from three dimensional bone image data of a patient's bone;

generating a surgical guide image from the bone surface image and an image of a prosthetic implant imposed on the bone surface image; and

generating control data from the generated surgical guide image, the control data being used to control operation of a machine to fabricate a surgical guide.

Thus, claim 1 recites a method wherein a *surgical guide* is fabricated based upon

(i) an image of a bone surface, and (ii) an image of a prosthetic implant.

2. Prima Facie Obviousness Has Not Been Established

The Examiner rejected claim 1 based upon the proposition that Lang discloses the limitations of claim 1 with the exception of control data but that Dore discloses generation of control data. (Office Action at page 4). The Examiner has mischaracterized Lang.

Specifically, the Examiner has alleged that the proposed combination results in the use of "image data to direct automatic construction of a prosthetic device." (Office Action at page 2). As stated above, however, claim 1 is not directed to the fabrication of a "prosthetic device." Rather, claim 1 is directed to the fabrication of a "surgical guide."

The Examiner maintains, however, that "a prosthetic device is in fact a surgical guide." (Office Action at page 3). This contention is in direct contradiction to the definition of a "surgical guide" provided in the Appellant's specification. Specifically, at page 4, line 19 through the end of page 5, the Appellant defines a "surgical guide" as a device that is used to assist in preparation of a bone to receive a prosthetic device and/or placement of the prosthetic device. Thus, a "guide" is "a jig that is designed to temporarily attach to anatomical landmarks in the region of the joint and is configured to permit a prosthetic component to be inserted through an opening in only one orientation."

Obviously, a prosthetic device cannot be inserted through itself or nor is it temporarily attached to anatomical landmarks in the region of the joint.

The Examiner further argues that “Applicant’s specification is ultimately directed to fabrication of a surgical prosthetic device.” (Office Action at page 3). Again, the Examiner’s argument is directly contradicted by the Appellant’s specification. At page 17, lines 13-18 of the Appellant’s specification, use of the disclosed system and method to fabricate a guide for “a standardized design for a prosthetic component to be implanted in the patient’s bone” is discussed. Thus, while the guide formed is unique to an individual (See, e.g., Appellant’s specification at page 13, lines 26-30), the prosthetic device ultimately implanted may be a standardized prosthetic device. Thus, the Appellant’s specification is ultimately directed to fabrication of a *guide* which can be used with any type of prosthetic device.

Therefore, a surgical guide is not the same as a prosthetic device. Thus, even if Lang is modified in the manner proposed by the Examiner, the proposed modification fails to arrive at the method recited in claim 1. Therefore, a *prima facie* case of obviousness has not been presented with respect to claim 1.

2. Lang Does Not Disclose the Recited Method

Additionally, the Examiner alleges that Lang discloses generation of a “surgical guide” at paragraph 28. (Office Action at page 6). The Examiner has mischaracterized the teaching of Lang.

Specifically, paragraph 28 of Lang is directed to “evaluating the fit of an articular repair system into a joint.” This is accomplished by “superimposing a three-

dimensional... or a two dimensional cross-sectional image ... of a joint and an image of an articular repair system.” Paragraph 28 does not provide any suggestion whatsoever of a “surgical guide image” as that term is used in the Appellant’s specification, i.e., an image of a device that is used to assist in preparation of a bone to receive a prosthetic device and/or placement of the prosthetic device.

Lang does include a discussion of the use of surgical tools at paragraphs 174 et seq. Therein, Lang discloses the use of “object coordinates that define the articular and/or bone surface and shape” with CAD/CAM techniques to adapt or select a device. (See, e.g., Lang at paragraph 175). Paragraphs 0176 and 0177 appear to describe what is meant by the language “adapt” and “select.” In these paragraphs, Lang appears to disclose using the disclosed techniques to determine settings for devices (object coordinates are “entered or transferred into the device”, paragraph 0176) or the selection of the best fit from a library of devices (paragraph 0177).

Thus, Lang appears to disclose using controls provided on a device to adjust settings on that device for a particular patient. Lang does not, however, disclose fabrication of a “guide” or the generation of an image of such a guide. Even if Lang could be construed as disclosing fabrication of a guide based upon an image of a bone surface, however, the Applicant has found nothing in Lang regarding the use of an image of a prosthetic device in addition to the use of a bone surface image to fabricate a guide.

Therefore, Lang, even when combined with Dore, fails to disclose fabrication of a *surgical guide* based upon (i) an image of a bone surface, and (ii) an image of a prosthetic implant as recited in claim 1.

3. Conclusion

Therefore, a *prima facie* case of obviousness has not been established with respect to claim 1. Moreover, none of the prior art cited by the Examiner discloses fabricating a *surgical guide* based upon (i) an image of a bone surface, and (ii) an image of a prosthetic implant as recited in claim 1. Therefore, the Board is respectfully requested to reverse the rejection of claim 1.

Discussion Regarding Patentability of Claims 2 and 4-7

Claims 2 and 4-7 were rejected based upon the same combination discussed above with respect to claim 1. Claims 2 and 4-7 depend directly from independent claim 1 and include the limitations discussed above with respect to claim 1 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 1, the Appellant respectfully submits that the obviousness rejections of claims 2 and 4-7 based upon Lang in view of Dore should be reversed.

Discussion re: Patentability of Claim 3

1. Claim 3

Claim 3 recites the following:

The method of claim 1, wherein the surgical guide image generation includes integrating at least one marker slot in the surgical guide image.

Accordingly, claim 3 requires a “marker slot” to be incorporated into the surgical guide image.

2. Discussion of Claim 1 Applies

As an initial matter, claim 3 depends from claim 1. Thus, claim 3 includes all of the limitations of claim 1. The Examiner rejected claim 3 based upon the same combination discussed above with respect to claim 1. Accordingly, for at least the same reasons set forth above with respect to claim 1, claim 3 is patentable over the proposed combination.

3. Lang does not Disclose a Marker Slot as Recited in the Claim

Additionally, the Examiner has alleged that Lang discloses at least one “marker”. (Office Action at page 7). The Examiner has misconstrued the claim.

Specifically, the Examiner alleges that Lang discloses a “marker” in paragraph 96. (Office Action at page 7). At paragraph 96, Land states:

Alternatively, each individual moveable element may include markers indicating the amount and/or degree they are deformed at a given spot. A camera can be used to intra-operatively image the device and the image can be saved and analyzed for curvature information. Suitable markers include, but are not limited to, actual linear measurements (metric or imperial), different colors corresponding to different amounts of deformation and/or different shades or hues of the same color(s).

Thus, Lang discloses the use of reference marks on a deformable component that can be used to identify the extent of deformation based upon image analysis of the markers. As used in the Appellant’s specification, however, a “guide marker slot” is an opening in the guide through which bone is viewable. Thus, page 8, lines 9-17 of the Appellant’s specification states:

The marker slots are formed in the cup portion of the jig proximate each of three flanges used to support the acetabular jig on the acetabulum. By inscribing a reference line on the acetabulum through a marker slot and also inscribing a reference line in the acetabulum in the areas of the bone

adjacent the marker slots, a surgeon is able to inscribe a staggered line on the acetabulum bone where the rim of the acetabular cup should rest. These reference marks facilitate a surgeon's ability to conform placement of the acetabular cup to the pre-operative plan template.

A mark on a component that is used to identify the extent of deformation of the component is not the same as a slot through which bone is viewable. Therefore, the marks of Lang are not the same as the "marker slot" recited in claim 3.

Therefore, even if Lang is modified in the manner suggested by the Examiner, such modification fails to arrive at the invention of claim 3. Accordingly, the Board of Appeals is respectfully requested to reverse the rejection of claim 3.

4. Conclusion

Therefore, for any of the reasons set forth above, claim 3 is patentable over the proposed combination and the Board of Appeals is respectfully requested to reverse the rejection of claim 3.

Discussion Regarding Patentability of Claim 8

Claim 8 was rejected based upon the same combination discussed above with respect to claim 1. Claim 8 recites:

A system for designing a surgical guide for a joint replacement prosthesis comprising:
 a bone surface image generator for forming a bone surface image from three dimensional bone anatomical data for a patient's bone;
 a surgical guide image generator for generating a surgical guide image from the bone surface image and an image of a prosthesis implant imposed on the bone surface image; and
 a surgical guide image converter for generating control data to control operation of a machine for fabricating a surgical guide that corresponds to the surgical guide image.

Thus, claim 8 recites a system which fabricates a *surgical guide* based upon (i) an image of a bone surface, and (ii) an image of a prosthetic implant. For purposes of this

rejection, this is the same limitation discussed above with respect to claim 1. Therefore, for at least the same reasons set forth above with respect claim 1, the Appellant respectfully submits that the obviousness rejection of claim 1 based upon Lang in view of Dore should be reversed.

Discussion Regarding Patentability of Claims 9 and 11-14

Claims 9 and 11-14 were rejected based upon the same combination discussed above with respect to claim 8. Claims 9 and 11-14 depend directly from independent claim 8 and include the limitations discussed above with respect to claim 8 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 8, the Appellant respectfully submits that the obviousness rejection of claims 9 and 11-14 based upon Lang in view of Dore should be reversed.

Discussion re: Patentability of Claim 10

1. Claim 10

Claim 10 recites the following:

The system of claim 8, wherein the surgical guide image generator integrates at least one marker slot in the surgical guide image.

Accordingly, claim 10 requires a “marker slot” to be incorporated into the surgical guide image.

2. Discussion of Claim 8 Applies

As an initial matter, claim 10 depends from claim 8. Thus, claim 10 includes all of the limitations of claim 8. The Examiner rejected claim 10 based upon the same

combination discussed above with respect to claim 8. Accordingly, for at least the same reasons set forth above with respect to claim 8, claim 10 is patentable over the proposed combination.

2. Discussion of Claim 3 Applies

Moreover, the “marker slot” of claim 10, for purposes of this appeal, is the same as the marker slot of claim 3. Accordingly, for at least the same reasons set forth above with respect to the marker slot of claim 3, claim 10 is patentable over the proposed combination.

4. Conclusion

Therefore, for any of the reasons set forth above, claim 10 is patentable over the proposed combination and the Board of Appeals is respectfully requested to reverse the rejection of claim 10.

Claims 15 and 17-21 are not Obvious

Claims 15 and 17-21 stand rejected under 35 U.S.C. § 103(a) as being obvious over Carson. Because the proposed modification of Carson fails to arrive at the claimed invention, the Board of Appeals is respectfully requested to reverse the rejection of claims 15 and 17-21.

Discussion Regarding Patentability of Claim 15

1. Claim 15

Claim 15 recites:

A system for aiding a surgeon in a joint replacement operation comprising:
 a patient bone data repository for storing three dimensional data of a patient's bone;
 a reference pointer for providing positional data of a surgical site;
 a registration module for (i) receiving the positional data, (ii) correlating the positional data for the surgical site obtained from the reference pointer to the three dimensional data for the bone stored in the patient bone repository, and (iii) determining changes in the surface of the bone using the received positional data; and
 an image generator for generating an image of the patient's bone with an image of a prosthetic implant imposed on the image of the patient's bone.

Thus, claim 15 recites a system which uses a reference pointer to generate data which is used by a registration module to determine changes in the shape of bone as the bone is being shaped.

2. Carson Does Not Disclose A Reference Pointer as Claimed

The Examiner rejected claim 15 based upon Carson. (Office Action at page 7). The Examiner has mischaracterized Carson.

Specifically, the Examiner has alleged that the “mouse [0094]” of Carson is a reference pointer. The only discussion of a “mouse” that the Appellant has identified is at column 10, lines 20-24, which appears to correspond to paragraph 94. There, Carson merely identifies a standard mouse used, for example, to move a cursor on a screen. Thus, a two-dimensional movement of the mouse is reflected on a screen. In contrast, a “reference pointer” as recited in claim 15 provides “positional data of a surgical site.” As discussed at page 18, lines 9-15, the positional data is a three dimensional coordinate location of the reference pointer. A device capable of producing two dimensional data is

not the same as a device which generates three dimensional data. Therefore, the “mouse” of Carson does not include the characteristics of a “reference pointer” as recited in claim 15.

Therefore, because Carson does not disclose a reference pointer with the characteristics required by claim 15, even if Carson is modified in the manner suggested by the Examiner, such modification fails to arrive at the invention of claim 15.

3. Carson Does Not Disclose a Registration Module as Claimed

The Examiner further alleged that Carson disclosed tracking changes made in the surface of bones. (Office Action at page 8). Carson has been mischaracterized.

Specifically, the Examiner has alleged that the determination of “bone spike holes” in Carson is the same as “determining changes in the surface of the bone using the received positional data.” As an initial matter, the determination of claim 15 is based upon data received from a reference pointer which the Examiner has alleged to be a mouse. The “bone spike hole” data, as disclosed at column 17, lines 9-19 of Carson, is not generated with a mouse. Therefore, even if “bone spike data” is used to track changes in a bone, the Examiner’s modification of Carson fails to arrive at the invention of claim 15 which requires the data to be received from a reference pointer.

Moreover, the “bone spike holes” are disclosed as “three features on the tibial trial.” (Carson at column 17, lines 13-15). Identifying the location of three features of a tibial trial is not the same as tracking changes made in the surface of a bone.

Therefore, because Carson does not disclose a registration module with the characteristics required by claim 15, even if Carson is modified in the manner suggested by the Examiner, such modification fails to arrive at the invention of claim 15.

4. Conclusion

Therefore, for any of the reasons set forth above, claim 15 is patentable over the proposed modification and the Board of Appeals is respectfully requested to reverse the rejection of claim 15.

Discussion Regarding Patentability of Claims 17-21

Claims 17-21 were rejected based upon the same art discussed above with respect to claim 15. Claims 17-21 depend directly from independent claim 15 and include the limitations discussed above with respect to claim 15 as well as other limitations. Therefore, for at least the same reasons set forth above with respect claim 15, claims 17-21 are patentable over Carson.

CONCLUSION

Claim 18 and the drawings do not recite structure not depicted in the drawings, claims 15 and 17-21 comply with the written description requirement, claims 1-15 and 17-21 are directed to statutory subject matter, claims 1-7 and 8-14 are not obvious over Lang in view of Dore, and claims 15 and 17-21 are not obvious over Carson.

Accordingly, the Board of Appeals is respectfully requested to reverse the rejections of claims 1-15 and 17-21.

Respectfully submitted,

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(8) CLAIMS APPENDIX

Claim 1. A method for designing a surgical guide for a joint replacement prosthesis comprising:

generating a bone surface image from three dimensional bone image data of a patient's bone;

generating a surgical guide image from the bone surface image and an image of a prosthetic implant imposed on the bone surface image; and

generating control data from the generated surgical guide image, the control data being used to control operation of a machine to fabricate a surgical guide.

Claim 2. The method of claim 1, wherein the bone surface image is formed from computed tomography data of the patient's bone.

Claim 3. The method of claim 1, wherein the surgical guide image generation includes integrating at least one marker slot in the surgical guide image.

Claim 4. The method of claim 1 further comprising:

controlling a laser with the control data to selectively crystallize a resin to form a surgical guide that corresponds to the surgical guide image.

Claim 5. The method of claim 1 further comprising:

controlling a machine tool with the control data to selectively cut a solid material to form a surgical guide that corresponds to the surgical guide image.

Claim 6. The method of claim 1 wherein the control data generation includes:
generating stereolithography data from the surgical guide image.

Claim 7. The method of claim 1 wherein the control data generation includes:
generating machine tool control data from the surgical guide image.

Claim 8. A system for designing a surgical guide for a joint replacement prosthesis comprising:

a bone surface image generator for forming a bone surface image from three dimensional bone anatomical data for a patient's bone;

a surgical guide image generator for generating a surgical guide image from the bone surface image and an image of a prosthesis implant imposed on the bone surface image; and

a surgical guide image converter for generating control data to control operation of a machine for fabricating a surgical guide that corresponds to the surgical guide image.

Claim 9. The system of claim 8, wherein the bone surface image generator generates a bone surface image from computed tomography data of a patient's bone.

Claim 10. The system of claim 8, wherein the surgical guide image generator integrates at least one marker slot in the surgical guide image.

Claim 11. The system of claim 8 wherein the control data generator generates stereolithography data for controlling a laser to selectively crystallize a resin to form the surgical guide.

Claim 12. The system of claim 8 wherein the control data generator generates computerized numerical control data for controlling a cutting tool to selectively cut a solid material to form the surgical guide.

Claim 13. The system of claim 8 wherein the surgical guide image generator generates the surgical guide image from a bone surface image of an acetabulum bone and an image of an acetabular cup.

Claim 14. The system of claim 8 wherein the surgical guide image generator generates the surgical guide image from a bone surface image of a femur bone and an image of a femoral stem.

Claim 15. A system for aiding a surgeon in a joint replacement operation comprising:
a patient bone data repository for storing three dimensional data of a patient's bone;
a reference pointer for providing positional data of a surgical site;
a registration module for (i) receiving the positional data, (ii) correlating the positional data for the surgical site obtained from the reference pointer to the three

dimensional data for the bone stored in the patient bone repository, and (iii) determining changes in the surface of the bone using the received positional data; and

an image generator for generating an image of the patient's bone with an image of a prosthetic implant imposed on the image of the patient's bone.

Claim 17. The system of claim 15 wherein the image generator generates the image in an orientation that corresponds to the angular orientation of the reference pointer with respect to a position on the bone.

Claim 18. The system of claim 15 wherein the reference pointer is an articulating arm with positional gyros mounted at pivotal joints of the articulating arm.

Claim 19. The system of claim 15 wherein the reference pointer communicates wirelessly with the registration module.

Claim 20. The system of claim 15 wherein the image generator generates an image of an acetabular cup on an image of a patient's acetabulum bone.

Claim 21. The system of claim 15, wherein the registration module is further configured to identify the portion of a bone remaining to be excised based upon the received positional data.

(9) EVIDENCE APPENDIX

None.

(10) RELATED PROCEEDINGS APPENDIX

None.